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**SUBSTITUTE SENATE BILL 5470**

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**State of Washington**

**59th Legislature**

**2005 Regular Session**

**By** Senate Committee on Health & Long-Term Care (originally sponsored by Senators Franklin, Thibaudeau, Keiser, Kline, Poulsen, Berkey, Haugen, McAuliffe, Rockefeller, Shin and Kohl-Welles; by request of Governor Gregoire)

READ FIRST TIME 02/28/05.

1           AN ACT Relating to importation of prescription drugs from Canadian,  
2 United Kingdom, Irish, and other nondomestic wholesalers; amending RCW  
3 18.64.046; adding a new section to chapter 18.64 RCW; and creating new  
4 sections.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

6           NEW SECTION. **Sec. 1.** The legislature finds that as consumers'  
7 prescription drug costs continue to rise, people across the state of  
8 Washington are seeking opportunities to purchase lower cost  
9 prescription drugs from Canada, the United Kingdom, Ireland, and other  
10 countries for their personal use. The state has a strong interest in  
11 promoting the safe use of prescription drugs by consumers in Washington  
12 state. To address this interest, the legislature intends to seek  
13 authorization from the federal government to license Canadian, United  
14 Kingdom, Irish, and other nondomestic prescription drug wholesalers,  
15 thereby providing licensed retail pharmacies the opportunity to  
16 purchase prescription drugs from approved wholesalers and pass those  
17 savings on to consumers, and providing consumers the opportunity to  
18 purchase prescription drugs from a trusted community pharmacist who is  
19 aware of all of their prescription drug needs.

1        NEW SECTION.    **Sec. 2.**    A new section is added to chapter 18.64 RCW  
2 to read as follows:

3        (1) By September 1, 2005, the board shall, in consultation with the  
4 department and the health care authority, submit a waiver request to  
5 the federal food and drug administration that will authorize the state  
6 of Washington to license Canadian, United Kingdom, Irish, and other  
7 nondomestic prescription drug wholesalers under RCW 18.64.046, thereby  
8 providing retail pharmacies licensed in Washington state the  
9 opportunity to purchase prescription drugs from approved wholesalers  
10 and pass those savings on to consumers. The waiver shall provide that:

11        (a) Canadian, United Kingdom, Irish, and other nondomestic  
12 prescription drug wholesalers meet the requirements of RCW 18.64.046  
13 and any rules adopted by the board to implement those requirements;

14        (b) The board must ensure the integrity of the prescription drug  
15 products being distributed by:

16        (i) Requiring that prescription drugs purchased from Canadian,  
17 United Kingdom, Irish, and other nondomestic wholesalers originate only  
18 from approved manufacturing locations;

19        (ii) Routinely testing prescription drugs purchased from Canadian,  
20 United Kingdom, Irish, and other nondomestic wholesalers for safety;

21        (iii) Establishing safe labeling, tracking, and shipping procedures  
22 for prescription drugs purchased from Canadian, United Kingdom, Irish,  
23 and other nondomestic wholesalers; and

24        (iv) Closely monitoring compliance with RCW 18.64.046 and any rules  
25 adopted to implement the waiver;

26        (c) The prescription drugs purchased from Canadian, United Kingdom,  
27 Irish, and other nondomestic wholesalers must be limited to those for  
28 which potential savings to consumers can be demonstrated and those  
29 available through purchase by individuals only at licensed retail  
30 pharmacies;

31        (d) To ensure that the program benefits those consumers without  
32 insurance coverage for prescription drugs who are most in need of price  
33 relief, prescription drug purchases from pharmacies under the waiver  
34 will be limited to those not eligible for reimbursement by third party  
35 insurance coverage, whether public or private; and

36        (e) Savings associated with purchasing prescription drugs from  
37 Canadian, United Kingdom, Irish, and other nondomestic wholesalers will  
38 be passed on to consumers.

1 (2) By December 1, 2005, the board, in consultation with the  
2 department and the health care authority, shall submit a detailed  
3 implementation plan to the governor and appropriate committees of the  
4 legislature that details the mechanisms that the board will use to  
5 implement each component of the waiver under subsection (1) of this  
6 section.

7 (3) The board shall adopt rules as necessary to implement this act.

8 **Sec. 3.** RCW 18.64.046 and 2004 c 52 s 3 are each amended to read  
9 as follows:

10 (1) The owner of each place of business which sells legend drugs  
11 and nonprescription drugs, or nonprescription drugs at wholesale shall  
12 pay a license fee to be determined by the secretary, and thereafter, on  
13 or before a date to be determined by the secretary as provided in RCW  
14 43.70.250 and 43.70.280, a like fee to be determined by the secretary,  
15 for which the owner shall receive a license of location from the  
16 department, which shall entitle such owner to either sell legend drugs  
17 and nonprescription drugs or nonprescription drugs at wholesale at the  
18 location specified for the period ending on a date to be determined by  
19 the secretary, and each such owner shall at the time of payment of such  
20 fee file with the department, on a blank therefor provided, a  
21 declaration of ownership and location, which declaration of ownership  
22 and location so filed as aforesaid shall be deemed presumptive evidence  
23 of the ownership of such place of business mentioned therein. It shall  
24 be the duty of the owner to notify immediately the department of any  
25 change of location and ownership and to keep the license of location or  
26 the renewal thereof properly exhibited in such place of business.

27 (2) Failure to conform with this section is a misdemeanor, and each  
28 day that the failure continues is a separate offense.

29 (3) In event the license fee remains unpaid on the date due, no  
30 renewal or new license shall be issued except upon compliance with  
31 administrative procedures, administrative requirements, and fees  
32 determined as provided in RCW 43.70.250 and 43.70.280.

33 (4) No wholesaler may sell any quantity of drug products containing  
34 ephedrine, pseudoephedrine, phenylpropanolamine, or their salts,  
35 isomers, or salts of isomers, if the total monthly sales of these  
36 products to persons within the state of Washington exceed five percent  
37 of the wholesaler's total prior monthly sales of nonprescription drugs

1 to persons within the state in March through October. In November  
2 through February, no wholesaler may sell any quantity of drug products  
3 containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their  
4 salts, isomers, or salts of isomers if the total monthly sales of these  
5 products to persons within the state of Washington exceed ten percent  
6 of the wholesaler's total prior monthly sales of nonprescription drugs  
7 to persons within the state. For purposes of this section, monthly  
8 sales means total dollars paid by buyers. The board may suspend or  
9 revoke the license of any wholesaler that violates this section.

10 (5) The board may exempt a wholesaler from the limitations of  
11 subsection (4) of this section if it finds that the wholesaler  
12 distributes nonprescription drugs only through transactions between  
13 divisions, subsidiaries, or related companies when the wholesaler and  
14 the retailer are related by common ownership, and that neither the  
15 wholesaler nor the retailer has a history of suspicious transactions in  
16 precursor drugs as defined in RCW 69.43.035.

17 (6) The requirements for a license apply to all persons, in  
18 Washington and outside of Washington, including those in Canadian  
19 provinces, the United Kingdom, Ireland, and other countries, who sell  
20 both legend drugs and nonprescription drugs and to those who sell only  
21 nonprescription drugs, at wholesale to pharmacies, practitioners, and  
22 shopkeepers in Washington.

23 (7) No wholesaler may sell any quantity of ephedrine,  
24 pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts  
25 of isomers, to any person in Washington other than a pharmacy licensed  
26 under this chapter, a shopkeeper or itinerant vendor registered under  
27 this chapter, or a practitioner as defined in RCW 18.64.011. A  
28 violation of this subsection is punishable as a class C felony  
29 according to chapter 9A.20 RCW, and each sale in violation of this  
30 subsection constitutes a separate offense.

31 (8) If the board is unable to develop a reciprocal licensing  
32 agreement with Health Canada or an applicable Canadian province, the  
33 United Kingdom, Ireland, and other countries, the board shall develop  
34 a process to license participating Canadian, United Kingdom, Irish, and  
35 other nondomestic wholesalers through on-site inspection and  
36 certification.

1        NEW SECTION.    **Sec. 4.**    If any part of this act is found to be in  
2    conflict with federal requirements that are a prescribed condition to  
3    the allocation of federal funds to the state, the conflicting part of  
4    this act is inoperative solely to the extent of the conflict and with  
5    respect to the agencies directly affected, and this finding does not  
6    affect the operation of the remainder of this act in its application to  
7    the agencies concerned. Rules adopted under this act must meet federal  
8    requirements that are a necessary condition to the receipt of federal  
9    funds by the state.

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